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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,935	02/15/2006	Kappei Tsukahara	082368-004400US	6397
20350 7590 05/13/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER ARCHIE, NINA	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 05/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/536,935

Applicant(s)

TSUKAHARA ET AL.

Examiner

Nina A. Archie

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/21/2003 and 2/15/2006.

### **DETAILED ACTION**

The office action on 1/25/2008 has been vacated.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Drawings***

The drawings in this application have been accepted. No further action by Applicant is required.

#### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Information Disclosure Statement***

The information disclosure statement filed on 11/21/2003 and 2/15/2006 has been considered. Initialed copies are enclosed.

#### ***Claim Rejections - 35 USC § 102 and 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, and 7-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsukahara et al WO 03/058233A1.

Claims 1-2 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis- inhibitory activity by binding assay with a membrane fraction expressing GWT1 protein to give inhibitors on transport of GPI anchor proteins. Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis-inhibitory activity, to give inhibitors on the transport of GPI anchor protein as antifungal agents. Tsukahara et al teach a DNA sequence (SEQ ID NO:1) that represents a gene of the

invention (see STIC RESULTS). Therefore Tsukahara et al teach a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI (GPI); and selecting the test sample that decreases GlcN-(acyl)PI, wherein the GWT1 gene is a DNA comprising the nucleotide sequence of SEQ ID NO: 1. Therefore Tsukahara et al anticipate a method, wherein the method further comprises a step 4, of determining whether the selected test sample inhibits the process of transporting a GPI-anchored protein to a fungal cell wall, whether the test sample inhibits the expression of a GPI-anchored protein on a fungal cell surface, or whether the test sample inhibits the proliferation of a fungi.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukahara et al WO 03/058233A1 in view of Cardoso De Almeida WO/1995/022614 Date August 24, 1995.

Claims 1-8 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Tsukahara et al is relied upon as set forth supra. However Tsukahara et al does not teach thin-layer chromatography.

Cardoso De Almeida et al teach GPI extraction to recover the glycoinositolphospholipid by using a series of organic solvent/aqueous extractions which can be analyzed using standard processes of thin layer chromatography. Cardoso De Almeida et al teach GPI moieties produced by engineered organism that can be purified and analyzed according to standard procedures such as solvent selective extraction and fractionation by thin layer chromatography (see Example 8).

It would have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Tsukahara et al and to incorporate into the method a detection by thin-layer

chromatography as taught by Cardoso De Almeida et al , because both Tsukahara et al and Cordoso De Almeida et al teach GPI proteins.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al US Patent 6,747,137 Date June 8, 2004 US Filing Date February 12, 1999 Tsukahara et al WO 03/058233A1 in view of Cardoso De Almeida et al WO/1995/022614 Date August 24, 1995.

Claims 1-8 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Weinstock et al teach a method of screening or testing for candidate anti-fungal compounds that impair *Candida albicans* comprising: a) providing fungal *Candida albicans* gene; b) providing one or more candidate compounds; c) contacting said gene with said one or more candidate compounds; and d) determining the ability of the candidate compound to inhibit gene activity. Weinstock et al teaches a method of screening test compounds for anti-fungal activity comprising providing a *Candida albicans* target sequence (see table 2 columns 587 and 588 contig3807) and contacting a test compound and determining binding of the test compound to said gene to determine whether said compound has anti-fungal activity ( i.e. whether anti-fungal inhibits activity (see column 10 lines 28-45, column 20 lines 46-67 to column 21 lines 1-54).

Weinstock et al teach is relied upon as set forth supra. However Weinstock et al does not teach method for screening compounds having fungal cell wall synthesis-inhibitory activity specifically GWT1 gene and thin layer chromatography.

Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis-inhibitory activity, to give inhibitors on the transport of GPI anchor protein as antifungal agents. Tsukahara et al teach a DNA sequence (SEQ ID NO:1) that represents a gene of the invention (see STIC RESULTS).



Cardoso De Almeida et al teach GPI extraction to recover the glycoinositolphospholipid by using a series of organic solvent/aqueous extractions which can be analyzed using standard processes of thin layer chromatography. Cardoso De Almeida et al teach GPI moieties produced by engineered organism that can be purified and analyzed according to standard procedures such as solvent selective extraction and fractionation by thin layer chromatography (see Example 8).

It would have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Weinstock et al and to substitute the gene as taught by Tsukahra et al because both teach method for screening antifungal compounds. It would also have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Tsukahara et al and to incorporate into the method a detection by thin-layer chromatography as taught by Cardoso De Almeida et al , because both Tsukahara et al and Cardoso De Almeida et al teach GPI proteins.

#### ***Status of the Claims***

No Claims are allowed.

Claims 1-8 are rejected.

#### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-0898. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie  
Examiner  
GAU 1645  
REM 3B31

/Mark Navarro/  
Primary Examiner